

What is claimed is:

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1. A composition comprising
- (a) a sustained release layer comprising
    - (i) a water-soluble polymer, and
    - (ii) a first pharmaceutically active agent; and
  - (b) a fast release layer comprising
    - (i) a matrix forming agent, and
    - (ii) a second pharmaceutically active agent.

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2. A composition as defined in claim 1, wherein the water-soluble polymer is selected from the group consisting of celluloses, cellulose ethers, polycarboxylated vinyl polymers, polyurethanes, gelatins, polysaccharide gums, seed gums, crosslinked alginate gum gels, and any combination of any of the foregoing.

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3. A composition as defined in claim 2, wherein the polycarboxylated vinyl polymer is selected from the group consisting of polyacrylic acid polymers, polyacrylic acid polymers crosslinked with polyalkenyl polyethers, and any combination of any of the foregoing.

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4. A composition as defined in claim 2, wherein the polysaccharide gum is selected from the group consisting of karaya gum, ghatti gum, and combination of any of the foregoing.

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5. A composition as defined in claim 2, wherein the seed gum is selected from the group consisting of guar gum, locust bean gum, psyllium seed gum, and any combination of any of the foregoing.

1                   6.       A composition as defined in claim 2, wherein the water-soluble  
2 polymer is selected from the group consisting of polyurethanes, gelatins,  
3 hydroxypropylmethylcellulose, sodium carboxymethylcellulose, methylcellulose,  
4 hydroxyethylcellulose, hydroxypropylcellulose, hydroxyethylmethylcellulose,  
5 hydroxyethylethylcellulose, hydroxypropylethylcellulose, carbopol, polyvinyl alcohol,  
6 dextran, chitosan, starches, polyacrylamides, polyacrylates, agar, collagen, fibronectin, alginic  
7 acid, pectin, hyaluronic acid, and any combination of any of the foregoing.

1                   7.       A composition as defined in claim 1, wherein the sustained release  
2 layer further comprises (iii) a fatty acid.

1                   8.       A composition as defined in claim 1, wherein the fatty acid is a  
2 hydrogenated vegetable oil.

1                   9.       A composition as defined in claim 1, wherein the first pharmaceutically  
2 active agent is selected from the group consisting of an anti-fungal agent, an anti-bacterial  
3 agent, a nutrient, a vitamin, a mineral, a diagnostic, a fertilizer, an insecticide, or any  
4 combination of any of the foregoing.

1                   10.      A composition as defined in claim 1, wherein the first pharmaceutically  
2 active agent is selected from the group consisting of metronidazole, miconazole nitrate,  
3 terconazole, chlorpheniramine maleate, pseudophedrine, detromethorphan, meclizine  
4 dihydrochloride, haloperidol, albuterol sulfate, dimenhydrinate, benzodiazepines, and any  
5 combination of any of the foregoing.

1                   11.      A composition as defined in claim 10, wherein the benzodiazepine is  
2 diazepam, lorazepam, or a congener thereof.

1                   12.     A composition as defined in claim 10, wherein the first  
2     pharmaceutically active agent is metronidazole.

1                   13.     A composition as defined in claim 1, wherein the sustained release  
2     layer comprises from about 5 to about 70% by weight of water-soluble polymer, based upon  
3     100% total weight of sustained release layer.

1                   14.     A composition as defined in claim 13, wherein the sustained release  
2     layer comprises from about 10 to about 50% by weight of water-soluble polymer, based upon  
3     100% total weight of sustained release layer.

1                   15.     A composition as defined in claim 14, wherein the sustained release  
2     layer comprises from about 10 to about 30% by weight of water-soluble polymer, based upon  
3     100% total weight of sustained release layer.

1                   16.     A composition as defined in claim 7, wherein the sustained release  
2     layer comprises up to about 15% by weight of fatty acid, based upon 100% total weight of  
3     sustained release layer.

1                   17.     A composition as defined in claim 16, wherein the sustained release  
2     layer comprises from about 5 to about 10% by weight of fatty acid, based upon 100% total  
3     weight of sustained release layer.

1                   18.     A composition as defined in claim 7, wherein the weight ratio of fatty  
2     acid to water-soluble polymer is about 2:5.

1                   19.     A composition as defined in claim 1, wherein the sustained release  
2     layer comprises a therapeutically effective amount of a first pharmaceutically active agent,  
3     based upon 100% total weight of sustained release layer.

1                   20.    A composition as defined in claim 1, wherein the sustained release  
2 layer comprises from about 15 to about 95% by weight of a first pharmaceutically active  
3 agent, based upon 100% total weight of sustained release layer.

1                   21.    A composition as defined in claim 20, wherein the sustained release  
2 layer comprises from about 50 to about 85% by weight of a first pharmaceutically active  
3 agent, based upon 100% total weight of sustained release layer.

1                   22.    A composition as defined in claim 1, wherein the sustained release  
2 layer further comprises

- 3                   (iv)   a preservative,
- 4                   (v)    a flavorant,
- 5                   (vi)   an antioxidant,
- 6                   (vii)  a surfactant,
- 7                   (viii) a sweetener,
- 8                   (ix)   a viscosity enhancer,
- 9                   (x)    a colorant,
- 10                  (xi)   a fragrance,
- 11                  (xii)  a plasticizer,
- 12                  (xiii) a lubricant,
- 13                  (xiv)  a filler,
- 14                  (xv)   a binder,
- 15                  (xvi)  a wetting agent,
- 16                  (xvii) a penetration agent,
- 17                  (xviii) a pH adjuster,
- 18                  (xix)  a disintegrant,
- 19                  (xx)   an excipient, or
- 20                  (xxi)  any combination of any of the foregoing.

1                   23.     A composition as defined in claim 1, wherein the sustained release  
2 layer has a specific gravity ranging from about 1.0 to about 1.2 g/mL.

1                   24.     A composition as defined in claim 1, wherein the sustained release  
2 layer provides a sustained release of the first pharmaceutically active agent.

1                   25.     A composition as defined in claim 1, wherein the sustained release  
2 layer provides a sustained release of the first pharmaceutically active agent for at least 6  
3 hours.

1                   26.     A composition as defined in claim 25, wherein the sustained release  
2 layer provides a sustained release of the first pharmaceutically active agent for at least 3 days.

1                   27.     A composition as defined in claim 1, wherein the matrix forming agent  
2 is selected from the group consisting of animal and vegetable protein derivatives, gums,  
3 polysaccharides, alginates, carboxymethylcelluloses, carrageenans, dextrans, pectins,  
4 polyvinylpyrrolidone, polyacrylic acid, polypeptide/protein complexes,  
5 polypeptide/polysaccharide complexes, sugars, inorganic salts, amino acids having from about  
6 2 to about 12 carbon atoms, and any combination of any of the foregoing.

1                   28.     A composition as defined in claim 27, wherein <sup>said</sup>the animal or vegetable  
2 protein derivative is selected from the group consisting of gelatins, dextrans, soy, wheat end  
3 psyllium seed proteins, and any combination of any of the foregoing.

1                   29.     A composition as defined in claim 27, wherein <sup>said</sup>the gum is selected from  
2 the group consisting of acacia, guar, agar, xanthan, and any combination of any of the  
3 foregoing.

1                   30.     A composition as defined in claim 27, wherein the matrix forming  
2 agent is a gelatin/acacia complex.

1                   31.     A composition as defined in claim 27, wherein the sugar is selected  
2 from the group consisting of mannitol, dextrose, lactose, galactose, cyclodextrin, and any  
3 combination of any of the foregoing.

1                   32.     A composition as defined in claim 27, wherein the inorganic salt is  
2 selected from the group consisting of sodium phosphate, sodium chloride, aluminum silicate,  
3 and any combination of any of the foregoing.

1                   33.     A composition as defined in claim 27, wherein the amino acid is  
2 selected from the group consisting of glycine, L-alanine, L-aspartic acid, L-glutamic acid, L-  
3 hydroxyproline, L-isoleucine, L-leucine, L-phenylalanine, and any combination of any of the  
4 foregoing.

1                   34.     A composition as defined in claim 33, wherein the amino acid is  
2 glycine.

1                   35.     A composition as defined in claim 27, wherein the matrix forming  
2 agent is selected from the group consisting of gelatin, pectin, soy fiber protein, and any  
3 combination of any of the foregoing.

1                   36.     A composition as defined in claim 35, wherein the matrix forming  
2 agent is selected from the group consisting of gelatin, pectin, and any combination of any of  
3 the foregoing.

1                   37.     A composition as defined in claim 1, wherein the second  
2 pharmaceutically active agent is selected from the group consisting of an anti-fungal agent, an

3 anti-bacterial agent, a nutrient, a vitamin, a mineral, a diagnostic, a fertilizer, an insecticide, or  
4 any combination of any of the foregoing.

1 38. A composition as defined in claim 1, wherein the second  
2 pharmaceutically active agent is selected from the group consisting of metronidazole,  
3 terconazole, miconazole nitrate, chlorpheniramine maleate, pseudophedrine, detromethorphan,  
4 meclizine dihydrochloride, haloperidol, albuterol sulfate, dimenhydrinate, benzodiazepines,  
5 and any combination of any of the foregoing.

1 39. A composition as defined in claim 38, wherein the benzodiazepine is  
2 diazepam, lorazepam, or a congener thereof.

1 40. A composition as defined in claim 38, wherein the pharmaceutically  
2 active agent is metronidazole.

1 41. A composition as defined in claim 1, wherein the fast release layer  
2 comprises from about 0.5 to about 15% by weight of a matrix forming agent, based upon  
3 100% total weight of fast release layer.

1 42. A composition as defined in claim 41, wherein the fast release layer  
2 comprises from about 0.5 to about 10% by weight of a matrix forming agent, based upon  
3 100% total weight of fast release layer.

1 43. A composition as defined in claim 42, wherein the fast release layer  
2 comprises from about 4 to about 10% by weight of a matrix forming agent, based upon 100%  
3 total weight of fast release layer.

1 44. A composition as defined in claim 1, wherein the fast release layer  
2 comprises (A) from about 4 to about 8% by weight of a matrix forming agent and (B) from

about 1 to about 20% by weight of an amino acid having from about 2 to about 12 carbon atoms, based upon 100% total weight of fast release layer.

45. A composition as defined in claim 1, wherein the fast release layer comprises a therapeutically effective amount of the second pharmaceutically active agent.

46. A composition as defined in claim 1, wherein the fast release layer comprises from about 15 to about 95% by weight of a second pharmaceutically active agent, based upon 100% total weight of fast release layer.

47. A composition as defined in claim 46, wherein the fast release layer comprises from about 60 to about 90% by weight of a second pharmaceutically active agent, based upon 100% total weight of fast release layer.

48. A composition as defined in claim 1, wherein the fast release layer further comprises from about 4 to about 8% by weight of matrix forming agent, from about 3 to about 5% by weight of at least one amino acid, and from about 2 to about 5% by weight of mannitol, based upon 100% total weight of fast release layer.

49. A composition as defined in claim 1, wherein the fast release layer further comprises

- (iii) a preservative,
- (iv) a flavorant,
- (v) an antioxidant,
- (vi) a surfactant,
- (vii) a sweetener,
- (viii) a viscosity enhancer,
- (ix) a colorant,
- (x) a fragrance,



- 11 (xi) a plasticizer,
- 12 (xii) a lubricant,
- 13 (xiii) a filler,
- 14 (xiv) a binder,
- 15 (xv) a wetting agent,
- 16 (xvi) a penetration agent,
- 17 (xvii) a pH adjuster,
- 18 (xviii) a disintegrant,
- 19 (xix) an excipient, or
- 20 (xx) any combination of any of the foregoing.

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1                    54.    A method of preparing a composition comprising  
2                    (a)    preparing a first aqueous solution containing (i) a water-soluble  
3 polymer and (ii) a first pharmaceutically active agent;  
4                    (b)    preparing a second aqueous solution containing (i) a matrix  
5 forming agent, and (ii) a second pharmaceutically active agent;  
6                    (c)    pouring the first and second aqueous solutions into a container;  
7                    (d)    freeze-drying the solution in the container to produce the  
8 composition.

1                    55.    A composition as prepared by a method as defined in claim 54.

*add A2*  
*add D5*